

## REMARKS

This response is submitted after final action pursuant to 37 CFR 1.116 because Applicants believe that elected species claim 5 is in condition for allowance. In any event entry of this response will place the application in better form for appeal. Applicants have raised no new issues and have added no new matter to the application. Finally the arguments presented herein are in direct response to points raised by the Examiner in the last office action and Applicants could not have filed their response at an earlier date.

Applicants wish to thank Examiner Puttlitz for conducting a telephone interview with their undersigned representative on 18 February 2010. During the telephone interview the undersigned maintained that the Applicants' crystalline nateglinide Form G as claimed in claim 5 with the specified Raman and IR spectral data is a different crystalline form of nateglinide from the Teva nateglinide Form G disclosed in published US Patent Application 2004/0116526A1, now US Patent 7,148,376 B1, as well as in the equivalent published US Patent Applications 2005/0075400; 2005/0014949; and 2004/0181089, cited by the Examiner in the central paragraph of page 2 of the office action mailed 29 January 2010. The undersigned maintained that the fact that both crystalline forms of nateglinide were designated by both Applicants and by Teva as nateglinide Form G is merely a coincidence.

Examiner Puttlitz indicated that in order for the Applicants to prove that there is a difference between their crystalline nateglinide Form G and the Teva crystalline nateglinide Form G, Applicants must show that the IR and Raman spectra of the prior art Teva nateglinide Form G crystals are different from the Applicants' nateglinide Form G crystals covered by elected species claim 5. The Examiner made it clear that if Applicants show that the claimed nateglinide Form G crystals have some physical characteristic distinguishing the claimed crystals from the nateglinide Form G crystals disclosed in the cited prior art references, the physical characteristics that distinguish the Applicants' new Form G crystals must be in the claim, and supported in the specification.

Applicants now have prepared nateglinide Form G crystals according to the Teva published US Patent Application 2004/0181089, paragraphs [0226] - [0031] and first of all performed X-Ray powder diffraction pattern measurement on the sample to confirm that the pattern agreed with the X-Ray powder diffraction pattern disclosed in US Patent Application 2004/0181089, and found that the diffractograms obtained were identical. Thus Applicants successfully synthesized the nateglinide Form G crystals disclosed in the prior art reference. Next Applicants performed both Raman and IR spectrograms on the prepared nateglinide Form G crystals according to US Patent Application 2004/0181089, and found significant differences in both the Raman and IR spectrograms for

the prior art Form G crystals and the presently claimed Form G crystals. In particular Applicants found that their nateglinide Form G crystals have an infra-red spectrum with intensive bands at 1763, 1735, 1614, 1533, 1180, 750, 574 and 491  $\text{cm}^{-1}$ ; and a Raman spectrum with intensive bands at 1762, 1710, 1182 and 822  $\text{cm}^{-1}$  as specifically recited in present claim 5, whereas the prior art Form G crystals do not have these intensive bands. Thus Applicants conclude that there is no doubt that the presently claimed nateglinide Form G crystals are significantly different from those crystals disclosed in the cited prior art references.

To support their findings Applicants are submitting a Declaration Under 37 CFR 1.132 signed by one of the Applicants Dr. Maria Gazdag. The declaration explains how the Applicants prepared the prior art nateglinide Form G crystals, how the Applicants used X Ray Diffraction Pattern Analysis to confirm that they prepared the prior art nateglinide Form G crystals, and how the Applicants carried out the Raman and IR spectral analysis of both the prior art and present forms of nateglinide Form G crystals. The declaration contains the X Ray Diffraction Pattern of the nateglinide Form G crystals of the prior art as well as a reproduction of the spectrogram of Figure 6 of US Patent Application 2004/0181089, to confirm the Applicants' successful synthesis of the prior art nateglinide Form G crystals, as well as the spectrograms showing the Raman and IR analysis of both the Applicants' nateglinide Form G crystals and those of the prior art.

Applicants have also included a table on page 5 of the declaration to show a side by side difference in the Raman and IR absorption bands for the Applicants' nateglinide Form G crystals and those of the prior art.

In view of the above direct comparative showing there should be no doubt that Applicants' nateglinide Form G crystals and those of the prior art are not the same and in fact have significantly different physical characteristics. Thus the Applicants ask that the Examiner no longer maintain his rejection of claim 5 as obvious under 35 USC 103 in view of US Patent Application 2004/0181089, and the other equivalent prior art references cited by the Examiner.

Now that Applicants have submitted directly comparative data to establish that their crystalline Form G of nateglinide is physically very different from the crystalline Form G of nateglinide disclosed in US Patent Application 2004/0181089, and the other equivalent prior art references, Applicants ask that the Examiner re-join process claims 1, 2 and 11, directed to the preparation of the Applicants' crystalline Form G of nateglinide, and examine these claims with claim 5. Under the PCT Practice the structure and the physical properties of the Applicants' crystalline Form G of nateglinide is a common technical feature linking all of these claims, that the prior art neither discloses nor suggests. Similarly Applicants also ask that the Examiner re-join process claim 7 as well because claim 7 is directed to a

process for preparing crystalline Form H of nateglinide where the Applicants' crystalline Form G of nateglinide is the starting material. Once again under the PCT Practice the structure of the Applicants' crystalline Form G of nateglinide is a common technical feature linking all of these claims, that the prior art neither discloses nor suggests.

Applicants believe that claims 1, 2, 5, 7 and 11 are patentably distinguishable over the cited prior art and that no rejection should be maintained against these claims in view of the cited prior art under either 35 USC 102 or 103. Thus Applicants believe that all of the claims are allowable and earnestly solicit a response to that effect.

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Enclosure: Declaration Under 37 CFR 1.132